

Attorney Docket No. 960296.98989
Applicant: Makielski et al.
Filing Date: August 1, 2003
Serial No.: 10/632,342
Art Unit: 1646
Office Action Date: 18 May 2007
Response Date: 18 October 2007
Examiner: Michael D. Pak

REMARKS

In an Office Action mailed May 18, 2007, the Examiner rejected the pending claims under 35 U.S.C. § 102(e), and restated and made final the requirement for restriction. The Examiner required cancellation of, or other appropriate action relating to, claims non-elected with traverse. Applicants respond to the rejection below. In view of the arguments presented herein, Applicants respectfully request reconsideration of the merits of this application.

A Request for Continued Examination accompanies this Response.

Restriction Requirement

Reference in the prior Office Action to Group VII is withdrawn. The Examiner apparently places Claim 48, in parts, into both of Groups V and VI. The Examiner seeks cancellation of the withdrawn claims. In response to a prior requirement for election of species, Applicants elected the polynucleotide of SEQ ID NO:7. For reasons detailed below, the independent claims, which are sufficiently broad to embrace both elected and non-species, are patentable over the cited art. Applicants respectfully suggest that the claims depending from those independent claims, including claims embracing previously non-elected species, should be rejoined into the application, examined and allowed. Rejoinder and consideration of the withdrawn claims is respectfully requested. In particular, Applicant requests rejoinder of Claims 3 - 6, 8, 9, 11, 12, 14-15, 21, 22, 24, and 26, which are maintained with a pendency status of "withdrawn."

Claims 30 - 50, drawn to claims not elected in response to the restriction requirement are canceled to expedite prosecution, without prejudice to the filing of a continuing application containing claims to the same subject matter.

Rejections Under 35 U.S.C. § 102(e)

Claims 1-2, 7, 10, 13, 16-20, 23, 25 and 27-29 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,342,357 to Splawski & Keating. As Applicants understand the Examiner's position, the polynucleotides embraced by the recited 'first

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polynucleotide' are outside the scope of the cited art, for these polynucleotides specify that the encoded polypeptides contain an arginine at position 1027. In contrast, the cited art only contemplates a encoding polypeptide having a glutamine at position 1027, and provides no disclosure, teaching, suggestion or motivation to provide a polynucleotide encoding arginine at this residue. Applicants have heretofore specified the relevance of the claimed sequences, and hereby incorporate those prior comments.

On the other hand, the recited 'second polynucleotide' and 'third polynucleotide' did not specify that the particular amino acid encoded at that position was maintained as an arginine. Applicants here amend independent Claim 1 to specify an arginine residue at that position. Notwithstanding any other permitted variation in the encoded polypeptide contemplated by the claim, the indicated encoded position is an arginine.

The recited 'fourth polynucleotide' itself refers back to the first three polynucleotides, and, at the sequence corresponding to position 1027 in the polypeptide, would necessarily encode the complement of a sequence that encodes arginine. Again, this is not disclosed in the cited art, which cannot, therefore, anticipate the claim.

The Examiner has acknowledged that Splawski & Keating nowhere disclose SEQ ID NO:8 by indicating the patentability of a polynucleotide that encodes SEQ ID NO:8 and of a cell comprising SEQ ID NO:8. Amended Claims 17 and 28, and Claim 18, are in condition for allowance. Applicants further believe that Claim 51 presented in the prior response, but not acknowledged in the office action as a pending claim, is also in condition for allowance, as it parallels Claim 18.

The other rejected claims are not within the scope of the cited patent. Applicants again submit that Splawski & Keating does not disclose every limitation and element as recited in the rejected claims, and incorporate their prior comments to this effect. None of the other rejected claims include the language of prior Claim 1 (as further clarified by the accompanying amendments). In particular, each of the other pending claims already recites that the encoded polypeptide has an arginine at position 1027. There can be no anticipation if the cited art does.

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not disclose each and every element set forth in the claim. Specifically, MPEP § 2131 provides:

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (noting that the identical invention must be shown in as complete detail as is contained in the claims) (emphasis added); *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed.Cir. 1989) (noting that the elements must be arranged as required by the claim).

Further, the cited art provides no motivation to modify position 1027 of the polypeptide there disclosed, or its encoding polynucleotide(s).

The amino acids encoded by the claimed polypeptides at the specified positions are biologically relevant. Applicants point the Examiner to paragraphs [0013], [0014], [0028] - [0034], and the Example in the application as filed, which highlight the importance of providing a standard genetic background when evaluating the effect of agents on cardiac sodium channels. Even though the polynucleotide of the cited document is similar to that of claimed polynucleotides, it is not found in that document nor does it teach the skilled person about the standard genetic background for this gene.

The importance of employing the most biologically relevant sequences when pre-clinical testing of agents cannot be overstated. While all claims retain the distinguishing structures of the main claims, the claims are sufficiently broad to embrace variation to those distinguishing structures, as the skilled person will appreciate the need to vary the polynucleotides (and encoded polypeptides) to ascertain the effect of changes on those structures.

In view of these remarks, Applicants respectfully request reconsideration of this rejection as applied to 1-2, 7, 10, 13, 16-20, 23, 25 and 27-29.

Fees

No additional claim fee is believed due in connection with this submission. However, if a fee is due, in this or any subsequent response, please charge the fee to Deposit Account No. 17-0055.

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A petition for an extension of time for two months accompanies this response so the response will be deemed to have been timely filed. Should any other extension of time be required in this or any subsequent response, please consider this to be a petition for the appropriate extension of time and a request to charge the petition fee due to the same Deposit Account.

Respectfully submitted,



Bennett J. Benson

Reg. No. 37,094

Attorney for Applicants

QUARLES & BRADY LLP

P.O. Box 2113

Madison, WI 53701-2113

TEL (608) 251-5000

FAX (608) 251-9166